

## **REMARKS/ARGUMENTS**

Claims 1, 2, 3, 5, and 6 remain in the application. Claims 1 and 2 have been amended. Claim 4 has been canceled. Reconsideration of this application, as amended, is respectfully requested.

Claim 1 and 2 have been amended to specify that the user interface comprises a numeric keypad and function buttons, the numeric keypad and function buttons capable of carrying out the functions of activating/deactivating power, selecting test or menu modes, editing entries, terminating entries, and activating a barcode reader as a substitute for manual numeric entry. Support for this amendment can be found at page 6, lines 4-6 of the specification.

Claim 1 was rejected under 35 U. S. C. §103 (a) as being unpatentable over Böcker et al. (US 5,507,288) in view of Karkar et al. (US 5,066,859). This rejection is respectfully traversed for the following reasons.

Böcker et al., U. S. Patent No. 5,507,288 (hereinafter "Böcker et al."), discloses an integrated analysis-element/sensor system comprising a sensor unit borne on the body of a patient and a central unit linked with the sensor unit by wireless data transmission. The central unit comprises the typical features of an evaluation instrument commonly used in element-analysis systems. It serves to evaluate an analysis-element in the form of a glucose test strip with a base layer and a test zone. The analysis-element is inserted into a test duct located beneath a flap of the central unit. A keypad is provided to operate the central unit. A display serves to display analytical data. An evaluation curve may be permanently stored in the central unit. Preferably, a separate, batch-specific evaluation curve is used for each new manufactured batch of analysis-elements and is transmitted to the central unit by means of a suitable data medium in machine-readable form. For that purpose, the central unit comprises a data reader, e.g., a barcode reader, to read a barcode affixed to the analysis-element itself or to an additional code carrier. The barcode is included in each pack of analysis-elements and contains the batch-specific evaluation curve.

Karkar et al., U. S. Patent No. 5,066,859 (hereinafter "Karkar et al."), discloses a blood analyzing device for measuring the hematocrit and oxygen

saturation levels of a quantity of blood. The preferred embodiment of the device comprises a housing having a keypad and display panel contained on the outer surface thereof. The measurements of hematocrit and oxygen saturation are compensated for the effects of pH and temperature. Both the pH and temperature values may be entered by the user through the utilization of keypad 18 on housing 12 before the actual test procedure begins.

According to claims 1 and 2 of the present application, the user interface of the hand-held analyte test instrument of this invention comprises a numeric keypad and function buttons, the numeric keypad and function buttons capable of carrying out at least one of the functions of activating/deactivating power, selecting test or menu modes, editing entries, terminating entries, and activating a barcode reader as a substitute for numerical entry. The hand-held analyte test instrument of this invention also comprises a barcode reader. The keypad and barcode reader allow operators to enter a variety of data, including operator and patient identification numbers, strip control lot numbers, calibration codes, and to set other instrument parameters (e.g., date time, security intervals, display backlighting). The barcode reader is preferred for entry of test strip calibration data because it eliminates the need to visually verify a test strip code during each test.

Based on the forgoing characteristics of the hand-held analyte test instrument of this invention, it is clear that the hand-held analyte test instrument of this invention provides at least one significant improvement over the combination of Böcker et al. and Karkar et al. The hand-held analyte test instrument of this invention has both a barcode reader and numeric keypad. These features enable the user of the instrument to enter a variety of data in a variety of ways. Neither Böcker et al. nor Karkar et al. has both of these features.

In addition to the above-described improvement, the combination of Böcker et al. and Karkar et al. is impermissible for several reasons. In effect, the rejection is based on a piecemeal reconstruction of the prior art; that is, the rejection is based on extracting the disclosure of the barcode reader from Böcker et al. and extracting the disclosure of the keypad from Karkar et al., and combining these extracted features in the absence of any suggestion for

doing so. As another example, the hand-held analyte test instrument of this invention has a port for test strip. While Böcker et al. discloses a port for a test strip, Karkar et al. employs a syringe (reference numeral 8) for collecting a sample of blood for use in determination of hematocrit and oxygen saturation. Thus, it is clear that the blood collection device of Karkar et al. teaches away from the use of a test strip, and, furthermore, renders the combination of Böcker et al. and Karkar et al. impermissible for the reason that it is impermissible within the framework of 35 U. S. C. §103 to pick and choose from any one reference only so much of it as will support a given position (i.e., a keypad for manual numeric entry), to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art (i.e., a syringe for collecting a sample of blood). As still another example, Karkar et al. has no need to use a barcode reader and Böcker et al. has no need to use a numeric keypad. Therefore, there is no suggestion in Karkar et al. to add a barcode reader to the analyzer described therein, and there is no suggestion in Böcker et al. to add a numeric keypad to the integrated analysis-element/sensor system described therein. Again, the combination of Böcker et al. and Karkar et al. is impermissible because neither Böcker et al. nor Karkar et al. suggests to one of ordinary skill in the art to combine a barcode reader and a keypad in a user interface in a hand-held analyte test instrument.

For the foregoing reasons, it is submitted that the combination of Böcker et al. and Karkar et al. fails to render claim 1 obvious to one of ordinary skill in the art.

Claims 2 and 5-6 were rejected under 35 U. S. C. §103 (a) as being unpatentable over Böcker et al. (US 5,507,288) in view of Cargin, Jr. et al. (US 5,602,456) and Karkar et al. (US 5,066,859). This rejection is respectfully traversed for the following reasons.

Cargin, Jr. et al., U. S. Patent No. 5,602,456 (hereinafter "Cargin, Jr. et al."), discloses a battery pack system for providing rechargeable battery power for a portable data collection terminal and for enabling recharging while received in power supplying relation to such a terminal.

According to claims 1 and 2 of the present application, the user interface comprises a numeric keypad and function buttons, the numeric

keypad and function buttons capable of carrying out at least one of the functions of activating/deactivating power, selecting test or menu modes, editing entries, terminating entries, and activating a barcode reader as a substitute for numerical entry. The hand-held analyte test instrument of this invention also comprises a barcode reader. The keypad and barcode reader allow operators to enter a variety of data, including operator and patient identification numbers, strip control lot numbers, calibration codes, and to set other instrument parameters (e.g., date time, security intervals, display backlighting). The barcode reader is preferred for entry of test strip calibration data because it eliminates the need to visually verify a test strip code during each test.

Based on the forgoing characteristics of the hand-held analyte test instrument of this invention, it is clear that the hand-held analyte test instrument of this invention provides at least one significant improvement over the combination of Böcker et al. and Karkar et al. The hand-held analyte test instrument of this invention has both a barcode reader and numeric keypad. Neither Böcker et al. nor Karkar et al. has both of these features. These features enable the user of the instrument to enter a variety of data in a variety of ways.

In addition to the above-described improvement, the combination of Böcker et al. and Karkar et al. is impermissible for several reasons. In effect, the rejection is based on a piecemeal reconstruction of the prior art; that is, the rejection is based on extracting the disclosure of the barcode reader from Böcker et al. and extracting the disclosure of the keypad from Karkar et al., and combining these extracted features in the absence of any suggestion for doing so. As another example, the hand-held analyte test instrument of this invention has a port for test strip. While Böcker et al. discloses a port for a test strip, Karkar et al. employs a syringe (reference numeral 8) for collecting a sample of blood for use in determination of hematocrit and oxygen saturation. Thus, it is clear that the blood collection device of Karkar et al. teaches away from the use of a test strip, and, furthermore, renders the combination of Böcker et al. and Karkar et al. impermissible for the reason that it is impermissible within the framework of 35 U. S. C. §103 to pick and choose from any one reference only so much of it as will support a given

position (i.e., a keypad for manual numeric entry), to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art (i.e., a syringe for collecting a sample of blood). As still another example, Karkar et al. has no need to use a barcode reader and Böcker et al. has no need to use a numeric keypad. Therefore, there is no suggestion in Karkar et al. to add a barcode reader to the analyzer described therein, and there is no suggestion in Böcker et al. to add a numeric keypad to the integrated analysis-element/sensor system described therein. Again, the combination of Böcker et al. and Karkar et al. is impermissible because neither Böcker et al. nor Karkar et al. suggests to one of ordinary skill in the art to combine a barcode reader and a keypad in a user interface in a hand-held analyte test instrument. Although Cargin, Jr. et al. does disclose a battery pack system for providing rechargeable battery power for a portable data collection terminal and for enabling recharging while received in power supplying relation to such a terminal, Cargin, Jr. et al. fails to provide the suggestion needed to enable a permissible combination of the teachings of Böcker et al. and Karkar et al. Claims 5 and 6 depend from claims 1 and 2, respectively. Accordingly, the subject matter of claims 5 and 6 is not rendered obvious to one of ordinary skill in the art by the combination of Böcker et al., Cargin, Jr. et al., and Karkar et al.

For the foregoing reasons, it is submitted that the combination of Böcker et al., Cargin, Jr. et al., and Karkar et al. fails to render claims 2, 5, and 6 obvious to one of ordinary skill in the art.


Claim 4 stands rejected under 35 U. S. C. §103(a) as being unpatentable over Brown (US 5,307,263) in view of Cheung et al. (US 5,074,977). Claim 4 has been canceled. Accordingly, this rejection can be withdrawn.

In view of the foregoing, it is submitted that claims 1, 2, 3, 5, and 6 are in condition for allowance, and official Notice of Allowance is respectfully requested.

Respectfully submitted  
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